DOC-3007 (Rev. 9/99)

WISCONSIN Department of Corrections Health Services	EFFECTIVE DATE August 9, 2012	NUMBER
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SUBJECT **Hepatitis C Program**		PAGE 1 Of 15

Most persons with hepatitis C virus (HCV) develop chronic infection. Chronic HCV infection has an unpredictable course and a small but significant subset of person with chronic HCV develops progressive fibrosis of the liver that leads to cirrhosis. Once cirrhosis develops in persons with chronic infection, the risk of hepatocellular carcinoma (HCC) is about 1-4% per year. Chronic HCV infections pose a major health care problem as a leading cause of chronic liver disease and cirrhosis and increased risk of hepatocellular carcinoma (HCC). It is the leading cause of liver transplantation in the United States. Current approaches to disease management have improved and include screening, education, medical evaluation, and treatment.

These guidelines are designed to assist clinicians in the evaluation and treatment of patients and are not intended either to replace a clinician's judgment or establish a set procedure for all patients with a particular condition.

FORMS/RESOURCES:

- Hepatitis C Documentation Forms:
  DOC-3428 HCV Evaluation & Referral Care Plan
  DOC-3430 HCV Treatment Flow Sheet
  DOC-3429 Consent/Refusal Hepatitis C Treatment
  DOC-3453 Hepatitis C Treatment Candidate
- Education – Teaching Handouts:
  #1 Hepatitis C Facts
  #2 Information for Persons Infected with Hepatitis C
  #3 Responsibilities of Persons Infected with Hepatitis C who are not in Treatment
  http://www.cdc.gov/hepatitis/HCV/PDFs/HepCLivingWithChronic-BW.pdf
  http://www.cdc.gov/hepatitis/HCV/PDFs/HepCIncarcerationFactSheet-BW.pdf
  http://www.cdc.gov/hepatitis/HCV/PDFs/HepCIncarcerationFactSheet-BW_sp.pdf
  CDC Viral Hepatitis C Webpage
  http://www.cdc.gov/correctionalhealth/docs/CDCHep_HepC.pdf
- Laboratory Monitoring and Side Effect Management Tables; Drug Dose Modifications, CES-D Depression Scale

Guideline Table of Contents

physician assistant and documented in the medical record on the appropriate treatment documentation form, flow sheet, and progress notes. Prior authorization is also required before beginning treatment. Those who do not qualify or are not appropriate candidates for treatment are placed in monitoring. Treatment regimen is dependent on the genotype.

Step 4 – Monitoring of patients who do not qualify for treatment (pages 5-6) All patients with chronic HCV who are not on treatment should have a plan for monitoring. This includes periodic lab monitoring and an annual review.

Dosage Guidelines for Peg-Intron, Ribavirin, and Telaprevir (page 7) Provides weight based dosage charts for treatment.

End of Treatment (page 8)

Discharge (page 8)

Screening

- **Risk Factors prompting a Hepatitis C Ab (EIA)(Antibody) Test:** (Obtain based on identified risk factors or an elevated ALT) ***(This test is sent to the Wisconsin State Laboratory of Hygiene (WSLH)***
  - Past injection drug use,
  - Liver disease, hepatitis or liver problems, elevated ALT.
  - History of clotting factor concentrate produced before 1987,
  - Hemodialysis
  - Blood transfusion and transplants before 1992,
  - HIV positive
  - HBcAb positive

- Short-term sentenced patients unless clinically indicated should ordinarily not be tested for HCV. Those with risk factors should receive counseling and education (fact sheet) and encouraged to contact community HCV testing sites when appropriate.

Step 1 – Initial Evaluation of HCV Ab+ patients

- **For positive HCV Ab test result :**
  - Complete DPH Form 4151 Communicable Disease Report (No need to wait for PCR results)
  - Obtain a new blood specimen for the required confirmatory testing, a HCV **Qualitative** PCR *HCV Polymerase Chain Reaction (PCR) for ribonucleic acid (RNA).*
    - ***(This test is sent to the Wisconsin State Laboratory of Hygiene (WSLH) and requires special handling- see appendix)***

  - Those with a positive HCV **Qualitative** PCR result receive education and counseling about the disease, transmission, preventing further damage from the hepatitis C infection, and information how they can protect others.

  - Evaluate all for immunity to hepatitis A and B. If susceptible (i.e. not immune by test or

history), schedule immunization series for hepatitis A or B or both with Twinrix series of three.

- If HIV positive refer to immunology and follow their recommendations regarding HCV treatment.

- Scheduled for further evaluation, and history. 1) Inquire about any past HCV treatment and outcome; 2) try to establish duration of HCV infection by hx; 3) follow-up in 3-4 months.

- If the HCV **Qualitative** PCR is negative, the patient has cleared the virus and is not infectious and does not have to be followed for HCV. Counsel and schedule a repeat HCV **Qualitative** PCR test in six months to a year (If the most recent negative HCV **Qualitative** PCR was done at least 6 months after the positive HCV Ab test it need not be repeated unless a new HCV infection is suspected)

Step 2 Hepatitis C Treatment Contraindications

If any of the below conditions are present, STOP. No further HCV testing (i.e., HCV RNA, viral genotype) is indicated at his time. See Step 4 – Monitoring. Develop a medical monitoring plan and address any pertinent issues. If condition changes, reconsider for Hepatitis C treatment

- **Serious concurrent uncontrolled medical conditions**
  - History of a solid organ transplant (renal, heart, or lung)
  - Certain auto-immune disorders, e.g., auto-immune hepatitis
  - Serious concurrent medical diseases, such as severe hypertension, heart failure, coronary heart disease, COPD.
  - Uncontrolled endocrine disorders, e.g., diabetes, thyroid disease
  - Decompensated cirrhosis (bili $\geq$ 1.5, INR $\geq$ 1.5, alb < 3.5, ascites, encephalopathy)
  - Platelet Count less than 75,000/mm3 or ANC less than 1,500 cells/mm3.
  - Documented non-adherence to prior therapy or failure to complete pretreatment evaluation process
- **Severe uncontrolled psychiatric disease, particularly unstable Axis I diagnosis and depression with current suicidal risk.** (A Psychiatrist needs to complete a DOC-3453)
- **Hypersensitivity to minimum required treatment agents (interferon, ribavirin).**
- **Continuing illicit drug use or alcohol use in the last 6 months**
- **Patient will be incarcerated for an insufficient period of time to complete treatment**
  - **Generally inmates need at least 1 year to get through evaluation and treatment course, often it takes longer.**
  - **At least 1 year LOS needed at time of step 2 assessment – evaluation and treatment takes up to 12 months**
- **Pregnant** - Re-evaluate when no longer pregnant
- **Patient refuses evaluation or treatment**. See Consent/Refusal to Hepatitis C Treatment (DOC-3429)
- **If any one of the above seven contraindications are present, then STOP**. No further HCV testing (i.e. HCV viral load or genotype) is indicated at this time. See Step 4 monitoring. Develop a medical monitoring plan and address pertinent medical issues. If conditions change, reconsider for treatment.
- Previous genotype I patients who were relapsers or partial responders to PegIntron and ribavirin treatment may be considered for triple therapy on a case by case basis.

If no contraindications as listed above are present:

- Psychiatric clearance for past and present mental health issues. A psychiatrist needs to complete a DOC-3453 for any patient with an MH-2 classification and any patient on psychiatric meds for psychiatric diagnoses.
- Obtain ECG for patients with preexisting cardiac disease
- Exercise Stress test if ≥ age 45 or ≥ age 30 with family history of premature coronary artery disease
- Cardiac risk assessment is critical because hemolysis associated with ribavirin may precipitate angina pectoris.

Step 3 - Treatment Work-up

- Obtain informed consent
- Order and draw lab and send to DOC contracted laboratory:
  - HCV viral load & viral genotype
  - Baseline tests: CBCD, Platelets, TSH, INR, Creatinine, Ferritin, TIBC, ANA, U/A, uric acid, ALT, AST, total bili.
- Order Baseline EKG
- Order direct funduscopic exam with optometrist

Viral Genotype 1, 4, 5,6:

- Obtain IL 28B genotype for GENOTYPE 1 ONLY
- Determine need for liver biopsy
  - Use APRI score to guide discussion with patient:
    - If score is < 0.5, lower stage of fibrosis likely and patient should consider deferring biopsy and treatment.
    - If score is ≥ 0.5, higher stage of fibrosis more likely and patient may want to consider biopsy and treatment.
  - Biopsy required for type 1 and 4 unless cirrhosis already known to be present.
  - Biopsy done prior to referral to UW Hepatology for treatment
- If stage 2 fibrosis or higher, obtain Class II for treatment recommendation from UW Hepatology
- Genotypes 5 and 6 refer to UW for consultation.

Viral Genotype 2 or 3 :

- Obtain Class III for treatment recommendation from UW Hepatology
  - If approved obtain and initiate treatment recommendations from UW Hepatology
  - If denied counsel patient with Handout #3 and initiate Step 5 – Monitoring

Step 4 – Monitoring of patients who do not qualify for treatment

- It is important to have a plan for each patient.
- Outline the plan clearly in the Problem List and progress notes.
- Ensure baseline tests are in chart.

- Obtain ALT, AST, total bili, albumin, INR at six month intervals.
- Obtain CBCD yearly and (if genotype 1) calculate APRI score
- For patients with past liver biopsies, determine timing of possible re-biopsy. Determination of timing of re-biopsy for those patients whose treatment was deferred due to having stage 0 or 1 fibrosis on previous biopsy should be based on subsequent increases in the APRI score and/or evidence of steatosis or inflammation. Those who develop clinical evidence of hepatic dysfunction should also be priority candidates for re-biopsy.
- Annual review to assess patient status as regards both potential treatment candidacy and overall status of patient's liver function and related health issues.

Hepatocellular carcinoma monitoring: The risk for development of HCC does not begin until the development of cirrhosis has occurred. Therefore neither AFP (alpha fetoprotein) nor liver U/S or CT are indicated unless cirrhosis is known or strongly suspected. If so, perform AFP and U/S yearly.

Labs: Serum ammonia levels have no prognostic value outside of making a diagnosis of delirium and should be avoided. HCV viral loads and genotyping are not necessary unless treatment is indicated.

General Side Effect Management	
The Schering call line 1-800-640-2144 and/or UW specialists may be contacted for advice on dealing with side effects that are unusual or persistent.	
Flu-like effects (interferon)	Acetaminophen 650 mg as needed; no more than 3 times per day. Limit to first few injections; can be given at bedtime on days of injections; may use antihistamine for PM dosing of interferon; Adequate hydration (*10 glasses of water/day or more – can take weight in pounds, divide by 2 = number of ounces of fluid needed per day* – excludes caffeine beverages – need to replace with non-caffeine liquids
Fatigue (interferon)	Adequate hydration; modify activity – moderate exercise; assure appropriate caloric intake (Boost or Resource for consistent weight loss ≥ 10 pounds). Give high protein, low fat diet.
Rash (interferon, TVR)	Topical steroid cream for localized rash covering less than 50% of body area, diphenhydramine or hydroxyzine for diffuse pruritis. Advise that rash might be present for duration of treatment. Assess for other causes of rash. Rash occurs in 50% on triple therapy, if severe (> 50% of body area with vesicles) may need to discontinue TVR.
Insomnia (interferon)	Evaluate and treat as needed
Hematologic effects (ribavirin, interferon, TVR)	Dose reduction – see dosing modifications. Anemia is common, rates double when TVR added to interferon and ribavirin. Neutropenia from interferon managed as below. If interferon must be stopped then ribavirin and TVR must be discontinued as well. Thrombocytopenia, adjust INT.
Neuropsychiatric effects (irritability, depression)	Depression screen at baseline and monthly for several months. Refer to psychiatrist as indicated. Treatment – short acting SSRI (celexa) often effective for symptoms of irritability, short temper, and agitation.
Anorectal symptoms	Occur most commonly with telaprevir. Topical steroids or anesthetics, antihistamines at bedtime. Loperamide for diarrhea.
Injection site irritation	Rotate sites between abdomen, thighs, and arms
Alopecia	Hair will return after discontinuation of therapy
Ophthalmologic effects	Ophthalmologic consultation is necessary for complaints of visual impairments
Thyroid dysfunction	Monitor TSH levels – consult with UW if necessary

Recommended Laboratory Testing for Treatment Monitoring of dual therapy
(DOC Contract Laboratory is utilized unless otherwise indicated)

Test	Baseline	1st two weeks	Week 4	During Treatment	3 months &/or End of Treatment	Monthly times 6 Post Treatment	6 months After Completion of Treatment
Genotype	X						
Pregnancy (female)	X			X		X	
HCV RNA - Quantitative	X				X - Low		X
HCV RNA - Qualitative							
CBC	X	X	X	X			
Hemoglobin	X	X	X	X			
WBC	X	X	X	X			
Platelets	X	X	X	X			
INR	X						
ALT	X			X			
ANA	X						
Fe-TIBIC	X						
Ferritin	X						
Creatinine	X						
TSH	X			Q 3 months			
EKG	X						
U/A	X						

Dosing Guidelines

WEIGHT-BASED DOSING CHART FOR PEG-INTRON (1.5 micrograms/kg) plus RIBAVIRIN

WEIGHT-kg(lb)	PEG-INTRON	PEG-INTRON Volume-ml [Vial]	Ribavirin Dose-mg
40-50 (88-110)	64 MCG	0.4 [160/ ML	800
51-64 (112-141)	80 MCG	0.5 [160/ML]	800
65-75 (143-166	96 MCG	0.4 240/ML]	1000
76-85 (167-187)	120 MCG	0.5 240/ML]	1000
86-105 (189-231)	150 MCG	0.5 [300/ML]	1200
> 105 (>231	calculate based on weight	based on weight	1400

DOSE MODIFICATION CRITERIA & GROWTH FACTOR USE FOR PEG-INTRON 1.5 u k plus RIBAVIRIN

Hemoglobin ≤ 10 g/dL or has experienced a drop of > 3 gm/ml since last lab draw	▪ Reduce ribavirin dose by one-half (to 400-700 mg daily). ▪ Recheck Hb weekly until > 10. ▪ Notify UW Hepatology.
Hemoglobin ≤ 8.5 g/dL but > 7.0	▪ Decrease ribavirin to 200 mg ▪ Initiate epoetin 40,000 units, weekly for 4 wks, check Hb wkly ▪ Inform UW Hepatology provider
Hemoglobin < 7.0	▪ Decrease ribavirin to 200 mg daily for 1 week and arrange transfusion of packed RBCs ▪ If Hb rises to > 8.5, follow above instructions but give epoetin, 40,000 units twice per week. ▪ Inform UW Hepatology.
Cardiac History	▪ If patient has a reduction of hemoglobin of > 1 g/dL during any 4 week period of treatment, consider reducing ribavirin dose slightly (by 200-400 mg per day) until hemoglobin rises. If hemoglobin falls below 11 g/dL, discontinue treatment

Absolute Neutrophil Count (ANC)	▪ If ANC falls below 500 but > 100, reduce PEG Intron dose to one half of recommended dosage. Recheck ANC q2 wks. ▪ If ANC does not rise to > 500 in 2 weeks, initiate Neupogen 300 mcg, subQ, weekly for 4 weeks. ▪ If ANC < 100, discontinue treatment, increase Neupogen to twice weekly and inform UW Hepatology provider
Platelets	▪ If platelets fall below 30,000 but > 20,000, reduce PEG Intron by one-half and inform UW Hepatology. Recheck in one week. ▪ If platelet count drops below 20,000 discontinue treatment and let UW Hepatology know. . ▪

INTERFERON ALFA-2b/RIBAVIRIN COMBINATION DOSE MODIFICATION GUIDELINES		
Parameter	**Dose Reduction** Ribavirin 600 mg/day Interferon alfa-2b – 1.5 million IU 3 times/week	**Permanent Discontinuation of Combination Treatment**
Hemoglobin	▪ < 10 g/dL (reduce ribavirin) ▪ ***Cardiac History only*** – if any ≥ 2 g/dL decrease during any 4-week period during treatment reduce ribavirin/interferon alfa-2b	▪ Hemoglobin < 8.5 g/dL ▪ ***Cardiac history only*** – Hemoglobin < 12/g/dL after 4weeks of dose reduction
White Blood Count	▪ < 1.5 x 10^9 /L (reduce interferon alfa-2b)	▪ < 1 x 10^9 /L
Neutrophil Count	▪ < .75 x 10^9 /L (reduce interferon alfa-2b)	▪ < 0.5 x 10^9 /L
Platelet Count	▪ < 50 x 10^9 /L (reduce interferon alfa-2b)	▪ < 25 x 10^9 /L

End of Treatment

- Sustained Responders
  - Defined as no detectable virus six months after treatment as determined by HCV RNA
  - If HCV RNA is undetectable at end of treatment, obtain an HCV RNA test 6 months later to assess for an SVR. Obtain a final HCV RNA test 12 months post-treatment.

- Partial Responder
  - Achieved a ≥ 2 $\log_{10}$ reduction in HCV RNA, but still has detectable virus
  - Continue to monitor.

- Null responder
  - < 2 $\log_{10}$ reduction in HCV RNA
  - Continue to monitor

- Relapsers
  - Defined as undetectable viremia at end of treatment, but then subsequent detection of HCV RNA virus after treatment is stopped. HCV RNA is detectable at 6 months after completion of treatment.

Discharge

For veterans, refer to the Veterans Administration for treatment initiation or continuation and follow-up care.

If indigent, refer to a Federally Qualified Health Center (FQHC) in the area they will be residing. (List attached).

If patient is on treatment and cannot pay to have treatment continued, have the patient contact Merck's "The ACT Program, fax: 1-866-363-6389 or phone: 1-866-363-6379.

Provide patients with a release of information form and advise them to obtain copies of pertinent records for ongoing care. If discharge occurs while inmate on treatment, facilitate follow-up for medications and practitioner.

APPROVED:

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Bureau of Health Services — **DATE**

David Burnett, MD, MMM, Medical Director
Bureau of Health Services — **DATE**

Educational Handout #1

Check Out the Facts about Hepatitis C (HCV)

To be covered at time of HCV EIA Testing with this CDC education form (English) (Spanish)

Q: *What is hepatitis C?*

A: Hepatitis C is a liver disease caused by the hepatitis C virus (HCV), which is found in the blood of persons who have this disease. HCV is spread by contact with the blood of an infected person's an inflammation of the liver caused by a virus, drugs, or other factors. So far, there are 6 known kinds of viral hepatitis: A, B, C, D, E, & G. They differ in how they are transmitted as well as how long and how severely they can affect you. There is a vaccine for the prevention of hepatitis B, but not for hepatitis C.

Q: *How do I know if I have hepatitis C?*

A: There are several blood tests that can detect hepatitis C. One is the EIA (enzyme immunoassay). This is a screening test and could be false-positive (e.g. it appears positive but is really negative). If positive, a second test, qualitative polymerase chain reaction (PCR), is done to confirm virus is in the blood. A single positive PCR test indicates infection with HCV. A single negative test does not prove that a person is free from infection. Virus may be present in the blood and just not found by PCR. Also, a person infected in the past who has recovered may have a negative test. When hepatitis C is suspected and PCR is negative, a follow-up test may be ordered. Many persons with hepatitis C have no symptoms and do not realize they have the infection.

Q: *How do you "catch" hepatitis C?*

A: Hepatitis C is spread through contact with human blood, and perhaps through contact with other body fluids. You are at high risk for hepatitis C if you:

- Ever injected drugs using shared needles
- Had a blood transfusion or solid organ transplant before 1992
- Had long-term hemodialysis
- Have been in contact with the blood of someone who has hepatitis C.
- Have snorted drugs, or obtained tattoos or body piercing using shared paraphernalia
- Have multiple sexual partners.
- Have signs of liver disease (e.g. abnormal liver enzyme tests)
- Are a health care worker who has been exposed (e.g., needle sticks or splashes to the eye) to HCV-positive blood on the job.
- Were born to a HCV-positive mother
- Ever shared items such as razors, toothbrushes with an infected person who might have had his/her blood on them.

Q: *What if the HCV test is confirmed positive?*

A: The health services practitioner will order a test to measure the level of ALT (alanine aminotransferase, a liver enzyme) in the blood. If elevated, the practitioner will order further tests to determine possible liver disease, if treatment needs to be considered, and if specialist care is indicated. If the liver enzymes are normal, although unlikely, disease could still be present, and follow-up monitoring tests will be ordered.

Further information about hepatitis, how your liver works can be obtained from health services.

Educational Handout #2

Information for Inmates Infected with Hepatitis C

To be covered after a positive HCV PCR Test

A recent blood test showed that you had a positive hepatitis C virus (HCV) polymerase (PCR) test.

Q. *What is the next step?*

A. Contact your practitioner for further explanation and evaluation. You will be provided education and evaluation to determine if you are an appropriate candidate for treatment. Some medical conditions may necessitate waiting on treatment until your other medical conditions resolve or get better. You will be provided with protection from other hepatitis viruses by receiving hepatitis A and hepatitis B vaccinations.

Q. *What are the chances of persons with HCV infection developing long term infection, chronic liver disease, cirrhosis, liver cancer, or dying as a result of hepatitis C?*

A. Of every 100 persons infected with HCV, about:

- 75 to 85 persons may develop long-term infection
- 70 persons may develop chronic liver disease
- 15 persons may develop cirrhosis over a period of 20 to 30 years
- Less than 3% of persons may die from the consequences of long term infection (liver cancer or cirrhosis)

Q. *Can you have a normal liver enzyme (e.g. ALT) level and still have chronic hepatitis C?*

A. Yes. It is common for persons with chronic hepatitis C to have a liver enzyme level that goes up and down, with periodic returns to normal or near normal. Some persons have a liver enzyme level that is normal for over a year but they still have chronic liver disease. Your health care provider will determine how often to monitor your liver enzyme tests.

Fortunately, the virus is not easily transmitted to others, even with close contact and the majority of HCV infected people don't develop serious liver damage. Although there is FDA-approved therapy to try to cure people of the virus, the treatment (shots and pills) is hard to tolerate because of serious side-effects. Therefore, pharmacological treatment is used only where it is believed the treatment can lead to improvement, but not when the liver is so bad that it is already failing. A liver biopsy may be requested to determine if treatment is a good idea. For the few who do go on to develop disease from chronic HCV, 15 to 20 years may pass before serious damage such as cirrhosis of the liver or cancer develops. In some instances, you may be advised to wait for better safer treatments as the degree of liver injury is mild.

Q. *How can persons infected with HCV protect their liver from serious disease?*

A. There is a number of things people infected with HCV can do to slow or prevent the progressive liver damage from the virus.

- Not drinking any alcoholic beverages is very important since we know that people with HCV who drink heavily get much more damage and are more likely to develop cirrhosis.
- Having too much iron in your body can also promote damage from HCV. We check for excess iron in patients with HCV and provide treatment until levels are normal. We also recommend avoiding iron in vitamins and avoid taking high doses of vitamin C, which can activate iron inside the body.

- Being overweight and having poorly controlled diabetes seems to promote damage. In those cases, we strongly recommend losing weight. In diabetes, is very important for the disease to be well controlled. A well-balanced low calorie diet and an exercise program to lose weight will help limit damage from both the HCV and the diabetes.
- Do not use new medications or over-the-counter medications without first checking with your practitioner

Medical evaluation for HCV infection will be ordered by the health services practitioner as indicated.

Q. *How can persons infected with HCV prevent spreading HCV to others?*

- Don't ever shoot drugs. If you do shoot drugs, stop and get into a substance abuse program. Never share syringes, water (used for injections) or drug "works."
- Do not share personal care items that might have your blood on them such as toothbrushes, dental appliances, nail clippers, or razors.
- Cover you cuts and skin sores to keep from spreading HCV.
- Do not get a tattoo or any body piercing from an uncertified source.
- Remember HCV can spread by sex but it doesn't happen often. Sex with multiple partners increases the risk of getting HCV.

Q. *What other information should I be aware of?*

- HCV is not spread by sneezing, coughing, food or water, sharing eating utensils, or drinking glasses, or by casual contact.
- A person can be re-infected, as prior infection does not give protection against a different strain.
- Your practitioner will advise you regarding medical options according to the Department of Corrections Guidelines.
- Further information about hepatitis or how your liver works can be obtained from health services

Education Handout #3

Responsibilities of Inmates Infected with Hepatitis C

When Treatment is Not an Option

The following measures are suggested for persons with hepatitis C infections and pharmacological treatment is not an option.

1. If there is not enough time until your parole eligibility date to obtain treatment, it is your responsibility to contact your practitioner if you do not obtain parole and your stay is extended. A re-evaluation of treatment options for Hepatitis C may be possible.

2. If you stay less than a year, then it is your responsibility to obtain further care for your Hepatitis C in your community. Obtain your medical records completed in corrections for your practitioner when you return to the community.

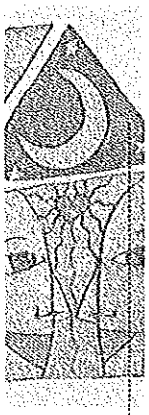
3. Always avoid all alcoholic beverages. If you have trouble avoiding alcohol or other illegal drugs, get help. Consider enrolling in a substance abuse program or participate in Alcoholics Anonymous or other support group.

4. Avoid taking iron supplements and avoid vitamins with iron. Avoid high doses of supplemental vitamin C (doses greater than 125 mg per day).

5. If you are overweight, try to adopt a healthy, well-balanced low calorie diet and develop a regular exercise program so that you can lose weight. Weight loss is beneficial for many reasons, but one of them is to protect your liver from HCV damage.

6. If you have diabetes, try to work with your doctor and nurse to obtain good control of your diabetes. Weight loss for overweight diabetics is very important.

7. Be careful with your blood and don't share razors, toothbrushes, etc. Review the information in Handout #1 & #2 that you were previously given. You can also receive more in-depth information about hepatitis C, how to protect your liver, and recommended medical monitoring from health services staff.



CES-D Scale

(Department of Health and Human Services, National Institute of Mental Health)

Circle the number for each statement that best describes how often you felt or behaved this way DURING THE PAST WEEK

During the Past Week	Rarely or none of the time (Less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	0	1	2	3
2. I did not feel like eating; my appetite was poor.	0	1	2	3
3. I felt that I could not shake off the blues even with help from my family or friends.	0	1	2	3
4. I felt that I was just as good as other people.	0	1	2	3
5. I had trouble keeping my mind on what I was doing.	0	1	2	3
6. I felt depressed.	0	1	2	3
7. I felt that everything I did was an effort.	0	1	2	3
8. I felt hopeful about the future.	0	1	2	3
9. I thought my life had been a failure.	0	1	2	3
10. I felt fearful.	0	1	2	3
11. My sleep was restless.	0	1	2	3
12. I was happy.	0	1	2	3
13. I talked less than usual.	0	1	2	3
14. I felt lonely.	0	1	2	3
15. People were unfriendly.	0	1	2	3
16. I enjoyed life.	0	1	2	3
17. I had crying spells.	0	1	2	3
18. I felt sad.	0	1	2	3
19. I felt that people disliked me.	0	1	2	3
20. I could not get "going."	0	1	2	3

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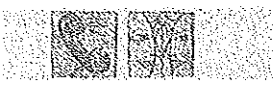

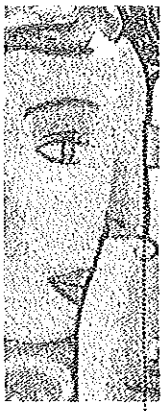

Center for Epidemiologic Studies Depression Scale (CES-D)/Monitoring Flow Sheet

Patient Name _____ Phone _____ Patient ID _____

Currently on antidepressant? ☐ Yes ☐ No Antidepressant/Dose _____

Prior history of depression? ☐ Yes ☐ No Prior antidepressant use? ☐ Yes ☐ No

Antidepressant/Dose _____

Month of Treatment	Date of Test	Your Initials	CES-D Score	Score>16? Yes/No	Intervention or Antidepressant/Dose
Baseline					
Month 1					
Month 2					
Month 3					
Month 4					
Month 5					
Month 6					
Month 7					
Month 8					
Month 9					
Month 10					
Month 11					
Month 12					

Center for Epidemiologic Studies Depression Scale (CES-D) Scoring

The CES-D consists of 20 questions. Patients are instructed to circle the number for each statement that best describes how often they felt or behaved this way during the past week. The score is the sum of the weights for the 20 items. **The weight for each item corresponds to the number chosen for each (0–3), except for items 4, 8, 12, and 16, which are reversed (3–0).** The possible range of scores for the scale is 0–60. The following cut-off scores best approximate the severity stages of depression: 0–9=none or minimal, 10–16=mild, 17–24=moderate, and >24=moderate to severe. **Scores greater than 16 have been considered to reflect the need for further assessment and evaluation of the patient for depression.**

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